

Office Action Summary

Application No.

10/537,401

Applicant(s)

TSUCHITA ET AL.

Examiner

Marsha M. Tsay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,16,20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,16,20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 20091201.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

In a telephonic interview with William Simmons on December 1, 2009, it was noted that the previous Office action included a rejection with a prior art not of record that was not necessitated by Applicants' amendment of the claims. It was acknowledged that the Office inadvertently issued a Final action. **Therefore, the finality of the previous Office action is withdrawn.** The previous Office action is replaced with the instant Non-Final action. All the rejections are the same and maintained herein.

This Office action is in response to Applicants' remarks received October 5, 2009.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 2-4, 7-15, 17-19, 22-23 are canceled. Claims 1, 5-6, 16, 20-21 are currently under examination.

Priority: The request for priority to JAPAN 2002-350200, filed December 2, 2002, is acknowledged. A certified copy of the foreign priority document has been filed in this case on June 2, 2005, and is in a non-English language.

Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-6, 16, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantman (US 4687782; IDS; previously cited) in view of Soop et al. (1988 J Appl Physiol 64(6): 2394-2399). Brantman discloses a composition consisting essentially of carnitine, isoleucine, leucine, valine, glutamine, and a whey protein, i.e. casein, soy protein, lactalbumin (col. 7 lines 30-50), adapted for use with water as a diet supplement for facilitating the adaptation of skeletal muscle and liver to a program of strenuous exercise. Brantman further discloses a method of supplementing the diet of an athlete by having the athlete drink a solution consisting essentially of leucine, isoleucine, valine, glutamine, and a whey protein, and having the athlete drink the solution (col. 6 lines 42-53). In col. 4 lines 45-50, Brantman discloses numerical ranges for the amino acids used in the composition: leucine (20-45 parts), isoleucine (15-40 parts), valine (15-40 parts), glutamine (10-30 parts), carnitine (0.3-2.0 parts), wherein the relative proportions of the amino acids are preferably within 20% of the recited ranges (col. 5 lines 20-25). It should also be noted that Brantman discloses that carnitine is an endogenous amino acid (col. 3 lines 55-63). Further, one of ordinary skill can see that out of all the amino acids used in said composition, carnitine is present in the smallest amount, i.e. 0.3 -2.0 g (col. 4 lines 45-50). Brantman further discloses that its composition is intended to provide the best metabolic milieu to permit and encourage protein synthesis in skeletal muscle (col. 4 lines 17-20). Brantman does not specifically teach a composition consisting of leucine, isoleucine, valine, glutamine, and a whey protein.

Soop et al. disclose the influence of carnitine supplementation on muscle substrate and carnitine metabolism during exercise. Soop et al. disclose that adequate muscle carnitine levels

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are maintained during exercise and that carnitine supplementation has no substantial effect on skeletal muscle metabolism under normal physiological conditions (p. 2399).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Brantman and formulate a composition consisting of isoleucine, leucine, valine, glutamine, and a whey protein, i.e. casein (claim 1, 5-6) and administer said composition to an athlete (claim I6, 20-21). One of ordinary skill would be motivated to administer said composition to an athlete and expect it to be successful in improving fatigue during exercise because Brantman teaches a composition consisting essentially of the branched amino acids, i.e. isoleucine, leucine, leucine, valine, glutamine, and a whey protein, which can be administered to promote muscle adaptation to strenuous exercise in a person. The motivation to exclude carnitine from said composition is suggested by Soop et al. which disclose that carnitine supplementation has no substantial effect on skeletal muscle metabolism, therefore, it would be reasonable for one of ordinary skill to exclude carnitine from the composition of Brantman since said composition of Brantman is intended to provide an optimum environment to permit and encourage protein synthesis in skeletal muscle and exogenous carnitine does not appear to have a substantial effect on skeletal muscle metabolism.

In their remarks, Applicants assert (1) Brantman aims to provide a supplement to maximize protein synthesis in skeletal muscle. Thus, because Brantman adds exogenous carnitine to provide the best metabolic milieu for maximizing protein synthesis, one of ordinary skill in the art would not readily have omitted carnitine from the composition of Brantman simply because it can be produced endogenously. Applicant's arguments have been fully

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considered and are persuasive to overcome Brantman as a single, primary 103(a) reference; however, they are not persuasive to overcome the use of Brantman as a 103(a) reference in view of Soop et al.

(1) Reply: The Soop et al. reference has been added as a secondary 103(a) reference. Brantman discloses that carnitine is an endogenous amino acid and that carnitine metabolism increases during exercise training. Brantman further discloses that carnitine is present in the smallest amount out of all the components in the composition of Brantman. Soop et al. disclose that adequate muscle carnitine levels are maintained during exercise and that carnitine supplementation has no substantial effect on skeletal muscle metabolism. Therefore, it would be reasonable for one of ordinary skill to exclude carnitine from the composition of Brantman since Soop et al. discloses that carnitine supplementation has no substantial effect on skeletal muscle metabolism.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

December 1, 2009

Marsha Tsay
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